K122175

Section 1 - Attachments

1-02. 510k Summary

MAR 2 8 2013

Official Correspondent:	CHRISTINE L. BRAUER, PH.D. US AGENT
Manufacturer/Submitter:	TECRES S.P.A. VIA A. DORIA 6 37066 SOMMACAMPAGNA VERONA – ITALY FDA OWNER/OPERATOR ID: 9033624
Date:	JULY 20, 2012
Trade/Proprietary Names:	MENDEC SPINE HV MENDEC SPINE HV SYSTEM
Common Name:	ACRYLIC RESIN FOR VERTEBROPLASTY/KYPHOPLASTY ACRYLIC RESIN FOR VERTEBROPLASTY/KYPHOPLASTY WITHIN A MIXING SYSTEM
Device Classification Name:	POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT
Classification Regulation:	21 CFR § 888.3027
Regulatory class:	CLASS II
Classification panel:	ORTHOPAEDIC
Classification Product Code:	NDN – CEMENT, BONE, VERTEBROPLASTY
Device Description:	Mendec Spine HV and Mendec Spine HV System are highly viscous, radio-opaque acrylic resins (PMMA based) for percutaneous vertebroplasty or kyphoplasty. These devices are made with the same raw material, but are supplied in different ways: • **Mendec Spine HV** is a traditional bone cement product: the liquid is contained in a vial and the powder in a sachet; these components are packaged in unitary PVC-blister with Tyvek lid, which is placed in an aluminum bag. • **Mendec Spine HV System** holds the powder and liquid components separately within a closed syringe-like device that serves as a mixing chamber. The device is packaged in unitary PVC-blister with tray, sealed with Tyvek lid, which is placed in an aluminum bag. The devices are sold disposable and sterile.
Indication for Use:	Mendec Spine HV / Mendec Spine HV System is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).
Substantial Equivalence:	This 510(k) submission demonstrates that the Tecres Mendec Spine HV and Mendec Spine HV System devices are substantially equivalent to the following predicate device:

- Kyphx HV-R Bone Cement (Kyphon Inc.), cleared in the 510(k) submission #K033801 and #K093828; and,
- Mendec Spine (Tecres), cleared in the 510(k) submission #K042415.

The intended use of Mendec Spine HV / Mendec Spine HV System is the same as the predicate devices, i.e. the treatment of pathological fractures of the vertebral body.

Mendec Spine HV and Mendec Spine HV System are equivalent in materials, mechanical and chemical-physical performances to the predicate devices. Mendec Spine HV System differs only for the configuration of the powder and liquid components that are enclosed within a ready to mix container.

Performance testing was conducted to verify the substantial equivalence to the predicate devices and their suitability to the intended use.
Tecres Mendec Spine HV devices were characterized through the following testing:

- mechanical: static and fatigue properties, viscosity; and,
- chemical-physical properties: setting-time, MMA release.

The safety and effectiveness of Mendec Spine HV / Mendec Spine HV System is adequately supported by the data and testing results.

Based on the same fundamental scientific technology and on the results of the verification activities, it is concluded that Tecres Mendec Spine HV / Mendec Spine HV System is substantially equivalent to legally marketed Kyphon Inc. Kyphx HV-R and Tecres Mendec Spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Tecres SpA
% Brauer Device Consultants
Christine Brauer, Ph.D.
Regulatory Affairs Consultant
7 Trail House Court
Rockville, Maryland 20850

Re: K122175
Trade/Device Name: Mendec Spine HV/Mendec Spine HV System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: February 25, 2013
Received: February 26, 2013

Dear Dr. Brauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: _____

Device Name: Mendec Spine HV / Mendec Spine HV System

INDICATIONS FOR USE STATEMENT

Mendec Spine HV / Mendec Spine HV System is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) and/or Over the Counter Use _____ (21 CFR 801 Subpart C)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122175